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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,366	03/15/2004	Edward F. Leonard	19240.145-US2	3154

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EXAMINER	
KIM, SUN U	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,366	LEONARD ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10-17 and 19-47* is/are pending in the application.

4a) Of the above claim(s) *21-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-17,19-20, 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 21-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. The Election has been treated as an election without traverse as noted in previous office action.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-7, 10-11, 14-15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication No. 2004/0009096 (hereinafter referred to as Wellman) in view of US Patent No. 3,799,873 (hereinafter referred to as Brown). Wellman teaches a membraneless dialysis device comprising three inlets (40, 41) and three outlets (43, 44) and a microfluidic extraction channel connected to three inlets and three outlets (see figure 10; paragraph [0060, 0067, 0068, 0071]). Recitation of "wherein laminar flows of a first extractor fluid, the sample fluid, and a second extractor fluid are established inside the extraction channel and wherein sheathing of the sample fluid by the first and second extractor fluids substantially

limits contact between the sample fluid and the surfaces of the extraction channel" in claim 1 is an intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). The extractor fluids is dialysate connected to first and third outer inlets and outlets in Wellman and the sample fluid is blood connected to second inner inlet and outlet (see Fig. 10). Claims 1 and 19 essentially differ from the membraneless dialysis device in reciting a recycle loop including a membrane device as a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels. Brown teaches a dialysis system including a recycle loop (16, 17) including a secondary processor such as hyperfilter membrane device (60) to purify the used or spent dialysate (see Fig. 1A-1D, 3B; col. 4, lines 1-12; col. 5, line 17 – col. 7, line 45). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the device of Wellman to incorporate a recycle loop including a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels to recycle dialysate fluid free of toxic solutes that are removed by hyper filter membrane as suggested by Brown (see col. 4, lines 1-12; col. 5, lines 27-32; col. 6, lines 64-66). Regarding claims 2-3, percentage of sample fluid being sheathed by the first and second extractor fluids are also intended use arose from laminar flow in the extraction channel. Regarding claim 4, Wellman teaches that some of water in blood exits the device with extractor fluid through an exit channel (44) (see paragraph 0068). Regarding claim 5, at low pressure differences, there is inherently no

advective transport of molecules within the extraction channel but pure diffusion in laminar flow condition in the apparatus of Wellman. Regarding claims 6-7, 10 and 14-15, two inlets (40) are connected with dialysate and sample fluid e.g. blood is connected to other inlet channel (41) and the sample flow e.g. blood flow is between two dialysate flows (see figure 10). Regarding claim 11, Wellman teaches that toxins are removed from blood (see paragraph 0071).

4. Claims 1-7, 10-11, 14-15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wellman in view of US Patent No. 3,939,069 (hereinafter referred to as Granger et al). Wellman teaches a membraneless dialysis device comprising three inlets (40, 41) and three outlets (43, 44) and a microfluidic extraction channel connected to three inlets and three outlets (see figure 10; paragraph [0060, 0067, 0068, 0071]). Recitation of "wherein laminar flows of a first extractor fluid, the sample fluid, and a second extractor fluid are established inside the extraction channel and wherein sheathing of the sample fluid by the first and second extractor fluids substantially limits contact between the sample fluid and the surfaces of the extraction channel" in claim 1 is an intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987). The extractor fluids is dialysate connected to first and third outer inlets and outlets in Wellman and the sample fluid is blood connected to second inner inlet and outlet (see Fig. 10). Claims 1 and 20 essentially differ from the membraneless dialysis device in reciting a recycle loop including a sorption device as a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels.

Granger et al teach a dialysis system including a recycle loop including a secondary processor such as activated carbon sorption device (7) to remove impurities from used or spent dialysate and reduce volume of required dialysate (see Figure; col. 2, line 43 – col. 4, line 13). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the device of Wellman to incorporate a recycle loop including a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels to recycle dialysate fluid free of toxic solutes that are removed by sorption device to reduce the require volume of dialysate to increase the speed and efficacy of hemodialysis as suggested by Granger et al (see Figure; col. 2, line 43 – col. 4, line 13). Regarding claims 2-3, percentage of sample fluid being sheathed by the first and second extractor fluids are also intended use arose from laminar flow in the extraction channel. Regarding claim 4, Wellman teaches that some of water in blood exits the device with extractor fluid through an exit channel (44) (see paragraph 0068). Regarding claim 5, at low pressure differences, there is inherently no advective transport of molecules within the extraction channel but pure diffusion in laminar flow condition in the apparatus of Wellman. Regarding claims 6-7, 10 and 14-15, two inlets (40) are connected with dialysate and sample fluid e.g. blood is connected to other inlet channel (41) and the sample flow e.g. blood flow is between two dialysate flows (see figure 10). Regarding claim 11, Wellman teaches that toxins are removed from blood (see paragraph 0071).

5. Claims 1-7, 10-14, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,948,684 (hereinafter referred to as Weigl et al '684) in view of US Pat. Publication 2003/0034306 (hereinafter referred to as Schulte et al) and Brown. Weigl et al '684

teach a microfluidic device comprising three inlet channels (55A, 55B and 50) and a common outlet channel connected to a microfluidic channel (100) wherein laminar flows of reference streams (75A, 75B) of same composition and sample stream (80) are established in the microfluidic channel (100) and the sheathing of sample stream by the first two reference streams substantially limits contact between the sample stream and the surfaces of the microfluidic channel (100) (see figure 3; col. 24, line62 - col. 25, line 45). Claims 1-4, 6-7, 14 and 19 essentially differ from the apparatus of Weigl et al '684 in reciting three exit channels and a recycle loop including a membrane device as a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels. Schulte et al teach a microfluidic device including multiple inlets and outlets connected to a microfluidic channel for establishing laminar flow and suggests that more or less inlets and/or outlets can be used depending on the microfluidic application or process for collecting sample of interest or waste or both (see figures 3-4; paragraphs 0023-0027). Brown teaches a dialysis system including a recycle loop (16, 17) including a secondary processor such as hyperfilter membrane device (60) to purify the used or spent dialysate (see Fig. 1A-1D, 3B; col. 4, lines 1-12; col. 5, line 17 – col. 7, line 45). It would have been obvious to a person of ordinary skill in the art to modify the apparatus and method of Weigl et al '684 to provide separate outlets to collect separate fractions of extraction fluid and sample fluid and to incorporate a recycle loop including a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels to recycle extractor fluid free of toxic solutes that are removed by hyper filter membrane as suggested by Brown (see col. 4, lines

1-12; col. 5, lines 27-32; col. 6, lines 64-66). Regarding claim 5, Weigl et al '684 teach that larger particles show no significant diffusion within the time the streams are in contact with each other in flow channel (100) (see col. 23, lines 23-27). Regarding claims 10-11, Weigl et al '684 teach that sample stream is blood and small ions such as protons and sodium ions diffuse rapidly across the channels (see col. 10, lines 48-67). Regarding claims 12-13, Weigl et al '684 teach the use of syringes in inlets and pumps in the outlet to adjust flow rate to accomplish equilibration of diffusion (see col. 17, lines 4-13; col. 24, lines 30-32; col. 28, lines 7-31). Regarding claim 16, Weigl et al '684 teach that the channel has a depth of at least about 200 micrometers (see col. 16, lines 12-16).

6. Claims 1-7, 10-14, 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl et al '684 in view of Schulte et al and Granger et al. Weigl et al '684 teach a microfluidic device comprising three inlet channels (55A, 55B and 50) and a common outlet channel connected to a microfluidic channel (100) wherein laminar flows of reference streams (75A, 75B) of same composition and sample stream (80) are established in the microfluidic channel (100) and the sheathing of sample stream by the first two reference streams substantially limits contact between the sample stream and the surfaces of the microfluidic channel (100) (see figure 3; col. 24, line62 - col. 25, line 45). Claims 1-4, 6-7, 14 and 20 essentially differ from the apparatus of Weigl et al '684 in reciting three exit channels and a recycle loop including a membrane device as a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels. Schulte et al teach a microfluidic device including multiple inlets and outlets connected to a microfluidic channel for establishing laminar flow and suggests that more

or less inlets and/or outlets can be used depending on the microfluidic application or process for collecting sample of interest or waste or both (see figures 3-4; paragraphs 0023-0027). Granger et al teach a dialysis system including a recycle loop including a secondary processor such as activated carbon sorption device (7) to remove impurities from used or spent dialysate and reduce volume of required dialysate (see Figure; col. 2, line 43 – col. 4, line 13). It would have been obvious to a person of ordinary skill in the art to modify the apparatus and method of Weigl et al '684 to provide separate outlets to collect separate fractions of extraction fluid and sample fluid and to incorporate a recycle loop including a secondary processor for generating a processed extractor fluid from the extractor fluids from the first and third outlets and return the processed extractor fluid to the first and third inlet channels to recycle dialysate fluid free of toxic solutes that are removed by sorption device to reduce the require volume of dialysate to increase the speed and efficacy of hemodialysis as suggested by Granger et al (see Figure; col. 2, line 43 – col. 4, line 13). Regarding claim 5, Weigl et al '684 teach that larger particles show no significant diffusion within the time the streams are in contact with each other in flow channel (100) (see col. 23, lines 23-27). Regarding claims 10-11, Weigl et al '684 teach that sample stream is blood and small ions such as protons and sodium ions diffuse rapidly across the channels (see col. 10, lines 48-67). Regarding claims 12-13, Weigl et al '684 teach the use of syringes in inlets and pumps in the outlet to adjust flow rate to accomplish equilibration of diffusion (see col. 17, lines 4-13; col. 24, lines 30-32; col. 28, lines 7-31). Regarding claim 16, Weigl et al '684 teach that the channel has a depth of at least about 200 micrometers (see col. 16, lines 12-16).

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl et al '684

in view of Schulte et al and Brown as applied to claim 14 above, and further in view of US 2002/0052571 (hereinafter referred to as Fazio). Claim 15 essentially differs from the apparatus of Weigl et al '684 in view of Schulte et al and Brown in reciting that the source of sample fluid is a human being connected to a second inlet channel. Fazio teaches an extracorporeal artificial kidney comprising microfluidic channels wherein blood from a human being is provided to an inlet manifold of the microfluidic channels (see abstract; figures 2-3; paragraphs 0013-0016). It would have been obvious to a person of ordinary skill in the art to connect an inlet channel of Weigl et al '684 in view of Schulte et al and Brown to human being to arrive at an artificial kidney to remove waste out of blood stream by dialysis.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weigl et al '684 in view of Schulte et al and Brown as applied to claim 1 above, and further in view of US Pat. No. 5,932,100 (hereinafter referred to as Yager et al '100). Claim 17 essentially differs from the apparatus of Weigl et al '684 in view of Schulte et al and Leonard et al in reciting that the extraction channel has a width-to-height ratio of at least 10. Yager et al '100 teach that the microfluidic extraction channel having an aspect ratio of width to depth ratio of less than 50 allows significant minimization of the device size at moderate extraction channel flow rate as well as lower flow rates (see col. 8, lines 34-55). It would have been obvious to a person of ordinary skill in the art to modify the microfluidic channel of Weigl et al '684 in view of Schulte et al and Brown to have a width-to-height ratio of at least 10 to provide distinctive advantages suggested by Yager et al '100 in significant minimization of the device size at moderate extraction channel flow rate as well as usage of lower flow rates.

9. Claims 44-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 46-47 are allowed.

11. Applicant's arguments with respect to claims 1-7, 10-17, 19-20 and 44-47 have been considered but are moot in view of the new ground(s) of rejection. Wellman in view of Leonard et al and Weigl et al '684 in view of Schulte et al, Leonard et al and Yager et al '100 teaches the claimed inventions.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 3,619,423 teaches a dialysis system comprising a secondary

membrane device. U.S. Patent No. 4,094,775 teaches a dialysis system comprising the use of sorption device and membrane device for removing toxic solutes from dialysate.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John Kim

John Kim
Primary Examiner
Art Unit 1723

JK
August 9, 2006